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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,675	08/15/2006	Daniel Baumgartner	001227/0954	2286

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NEW YORK, NY 10038

EXAMINER

MERENE, JAN CHRISTOP L

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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04/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,675	Applicant(s) BAUMGARTNER ET AL.	
	Examiner JAN CHRISTOPHER MERENE	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-18, 25-27 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-18, 25-27, 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 16-18, 25-27, 32 are rejected under 35 U.S.C. 101 because applicant is reciting a process and a structure in the same claim and in such a way as to raise question as to whether the claim is directed to a process or to the apparatus, such that it is apparent that the applicant is attempting to cover both in the same claim. Ex parte Lyell, 17 USPQ2d 1548 (BPAI 1990). An individual claim should recite either a process (or method) or a structure (or device). In this case, the claims refer to both a method of and a device, thus the examiner is unclear which invention applicant is intending to cover.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 16-18, 25-27, 32 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites "A method of implanting an intervertebral implant [...] the intervertebral implant comprising [...] the method comprising the steps of [...]." Claim 25 recites "A method if implanting an intervertebral implant [...] the implant including [...]"

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the method comprising the steps of [...]." Claim 32 recites " a method of implanting an intervertebral implant [...] the intervertebral implant having [...], the method comprising the steps of [...]." Thus Claims 16, 25, and 32 respectfully recite a claim which claims both an apparatus and the method steps of using the apparatus, which is held to be indefinite under 35 U.S.C. 112, second paragraph. *IPXL Holdings v. Amazon.com, Inc.*, 430 F.2d 1377, 1384, 77 USPQ2d 1140, 1145 (Fed. Cir. 2005); *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990). Based upon applicant's amendment, the examiner will treat the instant claims as a method/process and will treat with art as best understood.

Claim Rejections - 35 USC § 103

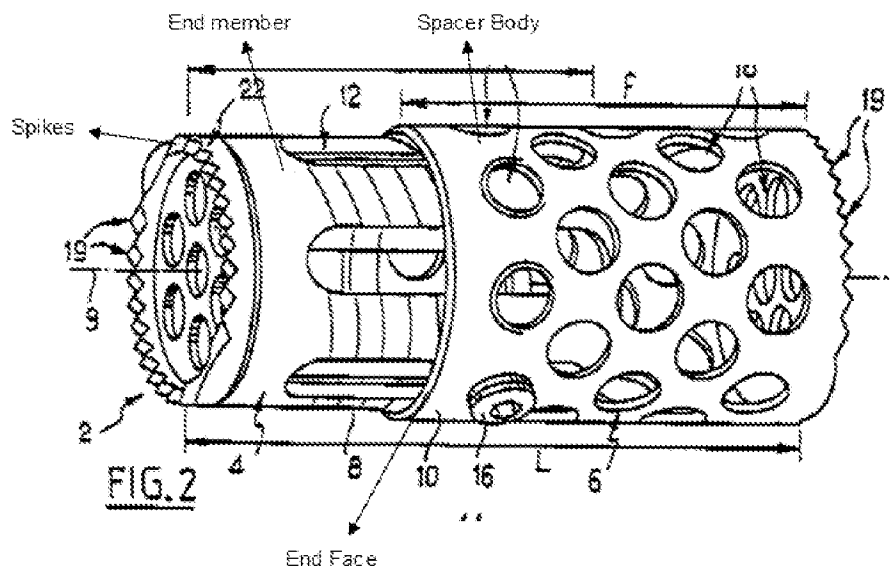
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. **Claims 16-17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Crozet et al US 6,616,695.

Crozet discloses a method of implanting an intervertebral implant, wherein the implant has a spacer body with an upper endface and an end member with spikes (see fig below), where the implant is inserted into the intervertebral space, where endmember moves from a second position where the spikes do not extend beyond the endface and the endface contacts at least a portion of the upper vertebra to a first position where the spikes extend beyond the endface into the vertebra and then the end plate is secured to the spacer body (see Col 3 lines 37-67, where the length L of the implant depends on the patient, where it would have been obvious depending on the patient's need that the

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distance L would correspond with the spikes not extending beyond the endface, where the adjustment of L is carried out once the implant is in-situ, where it would be obvious that the end face would contact at least a portion of the upper vertebra and where the L would be finally adjusted so that the spikes extend into the upper vertebra).



Crozet teaches that the end member moves via threads (see Col 2 lines 60-63) and is secured to the spacer body (see Col 3 lines 37-57), but does not specifically disclose the end member non-rotatably slidably moves.

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to not have the threads of Crozet, wherein the end member would be capable of non-rotatably slidably movable between a first and second position (where the end member would still be held in place by screw #16), since it has been held that omission of an element and its function in a combination where the

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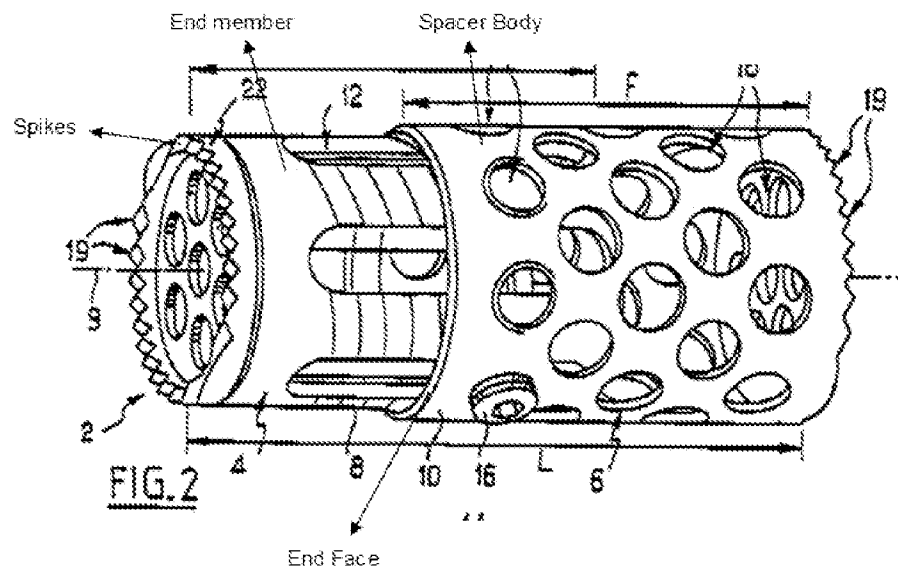
remaining elements perform the function as before involves only routine skill in the art.

In re Karlson, 136 USPQ 184.

6. **Claims 16-17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Crozet et al US 6,616,695 in view of Metz-Stavenhagen et al US 6,193,755.

Crozet discloses a method of implanting an intervertebral implant, wherein the implant has a spacer body with an upper endface and an end member with spikes (see fig below), where the implant is inserted into the intervertebral space, where endmember moves from a second position where the spikes do not extend beyond the endface and the endface contacts at least a portion of the upper vertebra to a first position where the spikes extend beyond the endface into the vertebra and then the end plate is secured to the spacer body (see Col 3 lines 37-67, where the length L of the implant depends on the patient, where it would have been obvious depending on the patient's need that the distance L would correspond with the spikes not extending beyond the endface, where the adjustment of L is carried out once the implant is in-situ, where it would be obvious that the end face would contact at least a portion of the upper vertebra and where the L would be finally adjusted so that the spikes extend into the upper vertebra).

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Crozet teaches that the end member moves via threads (see Col 2 lines 60-63) and is secured to the spacer body (see Col 3 lines 37-57), but does not specifically disclose the end member non-rotatably slidably moves.

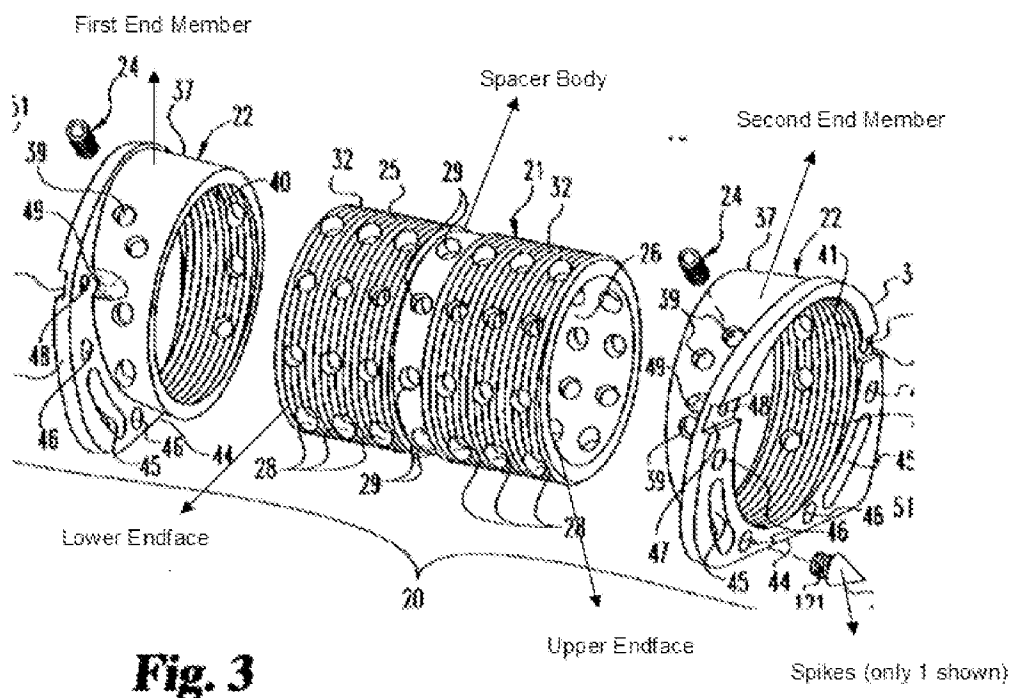
However, Metz teaches a similar device where the end member (#14) non-rotatably slidably moves in relation to a spacer body (#12 as seen in Figs 1-2 and see Col 3 lines 1-15).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Crozet so that it non-rotatably slidably moves as taught by Metz because it applies a known technique to a known device ready for improvement to yield predictable results of moving an end member in relation to a spacer body (see Col 3 lines 1-15).

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7. **Claims 16-17, 25-26, 32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbe et al US 5,776,198 in view of An et al US 6,866,682 and Doty US 4,599,086.

Rabbe discloses a method of implanting an implant, the implant having a spacer body with a lower and upper endface, first and second end members, each with a plurality of spikes (see fig below), where the implant is inserted into the intervertebral space and the first and second end members move from a second position to a first position where the spikes engage the vertebra (see fig below and see Col 6 lines 43-46, where spikes are provided to penetrate/engage the bone and see also Col 8 lines 1-27, where the end members move from a second position to a first position, where the spikes extend beyond the endfaces into the vertebra).



Rabbe also discloses the end members are threadably connected to the spacer body (as seen in Fig above, #41, #32) but does not specifically disclose the end members are slidably non-rotatably moved.

However, An teaches a similar device where an end member (#12) and a spacer body (#11) each with threads (#35, #90 respectfully), where they are non-rotatably slidably move in an extended and retracted position in relation to each other (see Fig 1, 12 and see Col 8 lines 58-60, Col 10 lines 59-67, where the inner surface containing the threads are located are configured so that the spacer body and end member can freely slide).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the threads, as well as the inner bores of the end members and external threads of the spacer body of Rabbe so that the pieces non-rotatably slidably moves from a second to first position (retracted/extended position) as taught by An because it applies a known technique to a known device ready for improvement to yield predictable results of moving an end member in relation to a spacer body (see Col 8 lines 58-60, Col 10 lines 59-67).

With regards to the lower and upper endfaces contacting the lower and upper vertebra, respectfully, (see Col 8 lines 13-20, where the implant is inserted between in the space and proper orientation of height is adjusted) the examiner notes that it would have been obvious that the endfaces would contact at least a portion of the vertebra depending on the patient's needs and anatomy and since the endplates are adjusted to accommodate the patient. Like wise, it would have also been obvious to one of ordinary

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skill to try and have the spikes retracted and not extend beyond the endfaces in order to properly align/insert the implant since the spikes extend from the end members.

Nevertheless, Doty teaches a spacer body (#12) with an upper and lower endface with spikes (#18, #20) that when inserted between the disc space, the spikes are at a second position where the spikes are retracted and do not extend beyond the endfaces, where the end faces of the body also contacts at least a portion of the vertebra and then the spikes are moved to a first position where they extend outward from the endfaces and engage the vertebra (see Fig 2-4, Col 3 lines 22-23, 26-36).

Furthermore, it would have also been obvious to one having ordinary skill in the art at the time the invention was made to modify the method Rabbe to have the spikes retracted so that they do not extend beyond the endfaces while being implanted, wherein the endfaces would also contact a portion of the vertebra since the spacer body is used to maintain spacing between the vertebra and the spikes do not engage outwardly from the end face, as taught by Doty because it applies a known technique to a known method ready for improvement to yield predictable results of inserting an implant with moveable spikes (Col 3 lines 22-23, 26-36).

8. **Claims 18, 27** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbe et al US 5,776,198, An et al US 6,866,682 and Doty US 4,599,086, as applied to claims 17, 26 above, in further view of Merlin US 4,840,291.

Rabbe, Metz and Doty disclose the claimed invention as discussed above where the end members have an inner surface of an internal bore (see above) but does not

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specifically disclose the elastically deformable projections extending from the inner surface.

However, Merlin teaches the use of an end member with an inner surface with elastically deformable projections (#68 as seen in Fig 7) engaging a spacer body (#3).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rabbe to include the elastically deformable projections as taught by Merlin above because it applies a known technique to a known device ready for improvement to yield predictable results of retaining an end member against a spacer body (see Col 4 lines 42-57).

Response to Arguments

9. Applicant's arguments with respect to claims above have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jan Christopher Merene/
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733